

What is claimed:

1. A process for preparing a devitalized soft tissue graft for implantation into a mammalian system, comprising:

extracting a soft tissue sample with an extracting solution comprising one or more non-denaturing detergents, to produce an extracted tissue;

washing said extracted tissue with water which is passed through a bed of hydrophobic adsorbent resin and anion exchange resin and subsequently inducing a pressure mediated flow of storage or decontaminating solution comprising one or more decontaminating agents and water replacement agents, through said extracted tissue, to produce said devitalized soft tissue graft; and storing said tissue in said solution;

wherein said devitalized soft tissue graft retains non-viable cells and/or cellular elements capable of inducing graft repopulation with the appropriate cell type.

2. A process for preparing a devitalized soft tissue graft for implantation into a mammalian system, comprising:

inducing a pressure mediated flow of an extracting solution comprising one or more non-denaturing detergents, through soft tissue, and washing said extracted tissue comprising inducing a pressure mediated flow of a water solution through a bed of hydrophobic adsorbent resin and anion exchange resin to produce extracted tissue;

subsequently inducing a pressure mediated flow of storage or decontaminating solution comprising one or more decontaminating agents and water replacement agents, through said extracted tissue, to produce said devitalized soft tissue graft; and storing said tissue in said storage solution;

wherein said devitalized soft tissue graft retains non-viable cells and/or cellular elements capable of inducing graft repopulation with the appropriate cell type.

3. The process of any one of claims 1 or 2, wherein said process does not comprise a denaturing detergent.

4. The process of any one of claims 1 or 2, further comprising, prior to washing, removing of processing reagents through use of hydrophobic and hydrophilic resins.

5. The process of any one of claims 1 or 2, wherein said extracting solution comprises one or more endonucleases.
6. The process of claim 5, wherein said one or more endonucleases comprise one or more broad-spectrum endonucleases capable of degrading both deoxyribonucleic acids and ribonucleic acids.
7. The process of claim 6, wherein said one or more broad-spectrum endonucleases comprise one or more recombinant endonucleases.
8. The process of claim 6, wherein said one or more recombinant endonucleases comprise BENZONASE® or PULMAZYME®.
9. The process of claim 5, wherein said one or more endonucleases are present in said extracting solution at a concentration sufficient to degrade nucleic acids present in said tissue sample.
10. The process of claim 9, wherein said one or more endonucleases are present in said extracting solution at a concentration of from about 20 U/ml tissue to about 400 U/ml tissue.
11. The process of claim 9, wherein said one or more endonucleases are present in said extracting solution at a concentration of about 375 U/ml tissue.
12. The process of any one of claims 1 or 2, wherein said extracting solution is a hypotonic buffered solution at an alkaline pH.
13. The process of any one of claims 1 or 2, wherein said extracting solution is recirculated through said soft tissue graft.
14. The process of any one of claims 1 or 2, wherein said decontaminating water solution is recirculated through said soft tissue graft.
15. The process of claim 3, wherein said water solution is recirculated through said soft tissue graft.
16. The process of any one of claims 1 or 2, wherein said water solution comprises USP grade, sterile, endotoxin-free, water.
17. The process of any one of claims 1 or 2, wherein said water solution is circulated through a bed of resin.
18. The process of any one of claims 1 or 2, wherein said resins are hydrophobic adsorbent

resins and anion exchange resins; where said resins are of the XAD and Amberlite family of resins.

19. The process of any one of claims 1 or 2, wherein said one or more decontaminating agents is selected from the group consisting of an antimicrobial agent, an alcohol, chlorine dioxide, polyethyleneimine, ethanol, isopropanol, methanol, glycerol, methylparaben, and an antibiotic.

20. The process of claim 19, wherein said decontaminating agents are non-reactive towards said one or more non-denaturing detergents.

21. The process of any one of claims 1 or 2, wherein said one or more water replacement agents are selected from the group consisting of polyol family, monoglycerides, monoolein, monolinolein, various short and long chain free fatty acids and their corresponding monoacylglycerol esters, glycerol, adonitol, sorbitol, ribitol, galactitol, D-galactose, 1,3 dihydroxypropanol, ethylene glycol, triethylene glycol, propylene glycol, glucose, sucrose, mannitol, xylitol, meso-erythritol, adipic acid, proline, hydroxyproline or similar water-soluble small molecular weight that can be expected to replace water in the base matrix structure of soft tissue and provide the hydrating functions of water in the tissue.

22. The process of any one of claims 1 or 2, wherein said storage solution comprises ultrapure, endotoxin-free, water or a water replacement agent.

23. The process of claim 19, wherein said chlorine dioxide or said methylparaben are present at a concentration in the range of from 0.001 % to 0.1 % (v:v).

24. The process of any one of claims 1 or 2, wherein said one or more decontaminating agents is selected from the group consisting of ethanol, isopropanol, methanol, glycerol, adonitol, sorbitol, ribitol, galactitol, D-galactose, 1,3 dihydroxypropanol, ethylene glycol, triethylene glycol, propylene glycol, glucose, sucrose, mannitol, xylitol, meso-erythritol, adipic acid, proline, and hydroxyproline.

25. The process of claim 24, wherein said one or more decontaminating agents are present at a concentration in the range of from 20% to 90% (v:v).

26. The process of any one of claims 1 or 2, wherein said extracting solution has an alkaline pH.

27. The process of claim 26, wherein said extracting solution further comprises one or more organic or inorganic buffers, wherein an alkaline pH is maintained, and an osmolality of the extracting solution which is hypotonic to the cells in said soft tissue is maintained.

28. The process of any one of claims 1 or 2, wherein said non-denaturing detergent comprise one or more detergents selected from the group consisting of N-lauroyl sarcosinate, deoxycholic acid, taurocholic, glycocholic, and cholic acids.

29. The process of claim 28, wherein said one or more non-denaturing detergents are present in said extracting solution at a concentration of from about 0.16 mM to about 64mM.

30. The process of claim 28, wherein said one or more non-denaturing detergents are present in said extracting solution at a concentration of from about 1.6mM to about 64 mM.

31. The process of claim 28, wherein said one or more non-denaturing detergents are present in said extracting solution at a concentration of from about 16mM to about 64mM.

32. The process of any one of claims 1 or 2, wherein said step of extracting is carried out for a period of time of from about 6 hours to about 40 hours.

33. The process of any one of claims 1 or 2, wherein said step of extracting is carried out for a period of time of about 12 hours to about 24 hours.

34. The process of any one of claims 1 or 2, wherein said extracting solution further comprises one or more decontaminating agents.

35. The process of claim 2, wherein one or more of said inducing and washing are carried out at a flow rate sufficient to carry away solutes dissolved in said extracting solution.

36. The process of claim 35, wherein said flow rate is from about 2 mls/minute to about 500mls/minute.

37. The process of claim 35, wherein said flow rate is from about 50 mls/minute to about 350 mls/minute.

38. The process of claim 35, wherein said flow rate is from about 150 mls/minute to about 250 mls/minute.

39. The process of claim 1, wherein said step of extracting is carried out for a time period of from about 6 hours to about 40 hours.

40. The process of claim 2, wherein said step of inducing is carried out for a time period of

from about 12 hours to about 40 hours.

41. The process of claim 39, wherein said time period is from about 16 to about 24 hours.
42. The process of claim 40, wherein said time period is from about 16 to about 24 hours.
43. The process of claim 1, wherein said step of extracting is carried out at a temperature of from about 4°C to about 42°C.
44. The process of claim 2, wherein said step of inducing is carried out at a temperature of from about 4°C to about 42°C.
45. The process of claim 43, wherein said temperature is from about 15°C to about 27°C.
46. The process of claim 44, wherein said temperature is from about 15°C to about 27°C.
47. A devitalized soft tissue graft, comprising: a soft tissue graft, said soft tissue graft including a soft tissue matrix retaining reproductively non-viable cells.
48. A devitalized soft tissue graft, comprising: a soft tissue graft, said soft tissue graft including a soft tissue matrix retaining metabolically non-viable cells.
49. A devitalized soft tissue graft, comprising: a soft tissue graft, said soft tissue graft including a soft tissue matrix retaining large molecular weight cytoplasmic proteins.
50. The devitalized soft tissue graft of any one of claims 47-49, wherein said devitalized soft tissue graft has tensile properties that approximate tensile properties of normal tissue.
51. The devitalized soft tissue graft of claim 50, further comprising a vein, an artery, or a heart valve.
52. The devitalized soft tissue graft of claim 50, further comprising a ligament or a tendon.
53. The devitalized soft tissue graft of claim 50, further comprising fascia, dura mater, meniscus, pericardium or skin.
54. The devitalized soft tissue graft of claim 49, further comprising a vein, an artery, or a heart valve.
55. The devitalized soft tissue graft of any one of claims 47 and 48, further comprising a ligament or a tendon.
56. A devitalized soft tissue graft produced by the process as claimed in any one of claims 1 or 2, wherein said devitalized soft tissue graft retains dimensions approximate to said soft tissue sample prior to processing.

57. A devitalized tissue graft, comprising: a soft tissue sample substantially free from reproductively viable cells and/or metabolically viable cells, produced by the process as claimed in any one of claims 1 or 2.

58. The devitalized soft tissue graft of any one of claims 47-49, wherein said devitalized soft tissue graft retains dimensions approximate to said soft tissue sample prior to processing.

59. A devitalized soft tissue graft produced by the process as claimed in any one of claims 1 or 2, wherein said devitalized graft is compatible to incoming cells such that the infiltrating cells are biochemically active and produce autologous collagen, elastin and proteoglycans such that the graft over time becomes autologous tissue.

60. A process for preparing a devitalized soft tissue graft for implantation into a mammalian system, comprising:

obtaining a soft tissue sample;

determining a tissue application for the soft tissue sample, the tissue application including a cardiovascular application and a musculoskeletal application;

employing an extensive devitalization method for the cardiovascular application;

employing a non-extensive devitalization method for the musculoskeletal application;

and

storing the tissue.

61. The process of claim 60, wherein the extensive devitalization method comprises longer treatment with endonucleases.

62. The process of claim 60, wherein the extensive devitalization method comprises longer treatment with detergents.

63. The process of claim 60, wherein the extensive devitalization method comprises more severe treatment with endonucleases.

64. The process of claim 60, wherein the extensive devitalization method comprises more severe treatment with detergents.

65. The process of claim 60, wherein the extensive devitalization method comprises treating tissues using ion exchange resins.

66. The process of claim 60, wherein the extensive devitalization method comprises treating tissues with extensive washing.